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(54) Title: FLEXIBLE SEALED COIL-LIKE DEVICES

(57) Abstract: The invention includes a medical device with a surface covering and coating that provides the device with desirable surface characteristics while optionally altering the surface area of the device, such that in the case of reusable devices they are easier to clean, and in the case of such devices as stents, the covering and coating provides a permanently adherent sheath resulting in an increased surface area. Optionally, the covering and coating is used as a drug reservoir for delivery of drug to specific locations.

FLEXIBLE SEALED COIL-LIKE DEVICES

Field of the Invention

The present invention relates to insertable medical devices with modified surface properties which improve the performance of the device during their use.

Background of the Invention

There is a need in the field of medical sciences, for a slippery yet medically safe surface for insertable medical devices so that the device can be inserted easily into the body without causing injury, infection, or excessive discomfort. Often it is desirable to have medication available on the surface of the medical device.

In the case of reusable devices, such as certain stylets, guide wires and flexible forceps for endoscopic use it is desirable that the exterior surface of the device not be breached, so as to prevent bodily fluid and/or tissue from accumulating inside the device. An unbreached surface allows reusable devices to be cleaned and sterilized with greater ease and effectiveness between procedures.

Vascular and other stents are also examples of insertable medical devices. The typical vascular stent configuration includes metal screen-like scaffolds which are inserted in a compressed form and then expanded at the target site. In the case of stents it is often desirable to have medication(s) available on the surface of the stent in order to cope with problems which arise either on the device surface or in adjacent patient tissue. However, these types of devices have very little surface area and therefore it is difficult to achieve high drug loading values on these surfaces.

Previous attempts at providing lubricious surfaces on wires typically have included a guide wire that is enclosed in a flexible plastic sleeve, however such a sleeve has limited elasticity. See U.S. Patent No. 4,925,445 issued to Sakamoto et al. U.S. Patent 5,443,907 issued to Slaikeu et al. describes a guide wire enclosed in a flexible plastic sleeve which has limited elasticity. A sleeve with insufficient elasticity can result in cracking and delamination during use. U.S. Patent No. 5,383,928 issued to Scott et al. describes a stent which is at least partially covered with a sleeve which contains one or more drugs, and which removably encompasses the stent. U.S. Patent No. 5,837,008 issued to Berg et al., describes a stent which has been coated with a polymer in which a variety of drugs have been entrapped. However, most drugs do not have high specific adhesion to metal surfaces, and therefore the presence of a drug at the metal surface can degrade the coating adhesion onto the metal device surface.

Thin coatings of TEFLON® also have been used on coil guide wires. Although such coatings can be flexible, they require baking at very high temperatures (~370°C), and adhering other coatings to such a TEFLON® coating can be extremely difficult. Polymeric extrusions have been made over coil and mandrel guide wires, but such extrusions are difficult to control, and it is difficult to achieve thin layer thicknesses over the long lengths (such as 150 cm.) that are required for some of the medical devices such as guide wires, forceps, trocars, catheters and stents.

Thus there is a need for an insertable medical device which has a coating which is flexible and elastic, and can be made in a cost effective manner.

Summary of the Invention

The present invention comprises a medical device comprising an insertable substrate,

an elastic polymeric covering adherent to the substrate, and a polymeric coating adherent to the covering, such that the coating and covering possess desirable surface characteristics such as lubricity, or lack thereof, as well as flexibility, expandability and elasticity. Such medical devices include but are not limited to guide wires, forceps, trochars, stents and catheters. In one embodiment the substrate can be a flexible structure such as a guide wire and the polymeric covering and coating is designed to be sufficiently flexible to allow the substrate to be bent around tight turns without the coating or covering delaminating or cracking.

Alternatively, the substrate may be a relatively rigid structure such as a vascular stent, in which case the flexible polymeric covering and coating is designed to be capable of expanding with the substrate without delaminating or cracking. For certain types of devices, when it is desirable for the surface to be lubricious in order to facilitate maneuvering the device, the covering and coating are designed to provide a lubricious surface. Other devices require non-lubricious surfaces in order to ensure that they remain in place once inserted. For such devices,the coating is designed to provide such a non -lubricious surface.

In the case of devices such as endoscopically used forceps, the covering and coating are designed to expand and fill the interstices between the solid substrate elements. By providing a continuous surface this can facilitate cleaning of the devices. The present invention contemplates a stent design which has a flexible elastic plastic coating permanently adherent to the stent surface. The coating expands with the stent and retains its integrity without any significant breaks in the coating layer. The substrate can be composed of a variety of metals or biodegradable, or preferably non-biodegradable polymers. Suitable coverings preferably include polyurethane, and suitable coatings preferably include a variety of hydrogels, comprising one or more components selected from the group consisting of

polyvinylpyrrolidone, epoxy resin, acrylic polymer, acrylic resin, and aliphatic polyisocyanate. Optionally, a binding layer or precoat can be applied to the substrate to enhance the binding of the coating to the substrate. Such precoats can contain polymers including but not limited to ethylene-acrylic acid copolymers, vinyl acetals, acrylate polymers and copolymers with functional groups which enhance adhesion onto substrates. Optionally, these coatings can contain crosslinking agents, including but not limited to melamine resins, isocyanates, phenolics, and epoxies. Examples of such technologies are described in U.S. Patent Application Serial No. 08/791,440, filed January 27, 1997, now allowed, which is incorporated herein by reference. Optionally, physiologically or pharmacologically active agents, such as antibiotics, anticoagulants, antiplatelet agents, antineoplastic agents, anti-angiogenic agents and angiogenic agents are incorporated into the coating. In the case of a stent, the coating may contain one or more drugs to, for example, prevent thrombus formation on the stent surface or restenosis in the surrounding tissue. Relatively high drug loading values are possible with the invention because the expansile and elastic covering and coating provides a higher surface area for drug loading.

The present invention also includes a method of modifying the surface properties of an insertable medical device by providing the substrate of the medical device with an elastic polymeric covering and polymeric coating such that the device has desirable surface properties such as lubricity or the lack thereof, while the coating and covering are flexible, elastic and expansile so that they can conform to the shape and other changes that the device experiences during its use. The invention also incorporates physiologically or pharmacologically active agents into the surface of the device, for delivery to selected sites.

Detailed Description of the Preferred Embodiments

The ease of use, effectiveness, and in the case of reusable devices, the cleaning of insertable medical devices is dependent to varying degrees on the surface properties of the device. A surface that is lubricious can permit the easier, safer and less uncomfortable insertion of a device. Similarly, a device that has a non-lubricious surface can be more securely fixed in a desired location, providing added safety and ease of use, and the inclusion of pharmaceutical or physiologic agents within the surface of a device can allow the delivery of such agents to desired locations. Examples of devices which could have added utility with such modifications include, but are not limited to, stylets, guide wires, flexible forceps used for endoscopic procedures, and vascular and other stents.

The present invention provides a surface to such medical devices such that improved surface characteristics can be provided to such medical devices. The medical devices contemplated in this invention comprise a substrate, a covering and a coating. The substrate forms the device or the outer surface of the device which is to be coated. The substrate is insertable into an animal, preferably a human patient. Such a substrate often has physical properties that are desirable for the functioning of the device but also providing inferior surface characteristics, such as for insertion or placement. The polymeric covering is adherent to the substrate surface, is flexible, such that it can be bent and flexed repeatedly without significant effect on its integrity, and/or elastic, such that it can change its shape and size under action of opposing forces, while retaining its ability to recover its original configuration when the forces are removed. The covering preferably is elastic, and able to expand to up to about 6 times its original diameter and/or length for use on expandable devices such stents. The covering preferably is elastic and flexible when applied to devices

such as endoscopic forceps or guide wires. Optionally the covering can be applied in one or more than one layer.

Covering the polymeric covering is a polymeric coating, which provides the desired surface characteristics to the medical device. The coating can be of the same composition as the covering, or can be of a different composition. The coating also has the properties of flexibility and elasticity, and optionally can be hydrophobic, hydrophilic or of intermediate hydrophilicity. The coating can be applied with one or more layers which may have the same or different composition. is one layer thick or optionally can be several layers thick. Together, the covering and the coating are preferably less than 100 μm thick, and more preferably less than 50 μm thick. The polymeric covering and coating preferably are sufficiently flexible so that articles coated with them are capable of being bent around tight turns, such as a 3 mm radius without breaking or delaminating. The flexible polymeric layer(s) preferably also are capable of expanding without significant delaminating or cracking.

The coating and covering preferably are applied to the substrate optionally by extrusion or by coating the substrate with a solution or with a dispersion of the selected polymer in a suitable solvent. Coating preferably is performed optionally by spraying or by dip-coating.

One preferred embodiment of the present invention is a vascular stent which is capable of being inserted into an animal in a collapsed state, placed into a desired location, and expanded to a diameter which can be larger, such as from about 1.5 to about 8 or more times larger than the collapsed size. The stent comprises a rigid but expandable framework. The coating and covering of the present invention preferably is sufficiently adherent, flexible and elastic such that when the stent is expanded, the coating and covering forms an adherent

sheath that is attached to the struts of the stent and stretches between them, providing a greatly increased surface area than would be provided by the struts of the stent alone. Optionally, the coating is non-lubricious, aiding in maintaining the stent in a desired location once the stent has been expanded. In yet another embodiment, the coating and optionally the covering, contain pharmacologically or physiologically active agents which are capable of being released and delivered to desired locations. Examples of such agents include, but are not limited to, antibiotics, anticoagulants, anti-platelet agents, antineoplastic agents, thrombogenic agents angiogenic agents and anti-angiogenic agents.

Optionally, one or more bonding layers can be used as a primer for the substrate surface to improve the bonding of the covering and coating to the substrate surface. Suitable bonding layers and their uses are described in Application Number PCT/US98/01531, which is incorporated herein, in its entirety, by reference. The bonding layers preferably are less than 10 μm, and more preferably less than 5 μm in thickness, and comprise one or more polymers which bond to the substrate, and to which other layers can be bonded.

The substrate of the device can be composed of a variety of materials. Examples include, but are not limited to, metals such as titanium, silver, gold, platinum, aluminum, chromium, stainless steel or tantalum, and shape memory materials, including but not limited to nickel/titanium alloys, copper/zinc alloys, and nickel/aluminum alloys. Other examples include polymeric materials including but not limited to biodegradable materials such as poly(L-lactic acid), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolicacid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates,

poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid as well as non-biodegradable materials such as polyurethanes, silicones, polyamides, polyimides, cellulose esters, cellulose ethers, cellulose ether/esters, and polyesters.

Examples of compounds that are used for the covering include but are not limited to polyurethane, polyvinyl acetals, acrylate polymers and copolymers, vinyl acetate polymers and copolymers, and rubbers such neoprene or silicone. Optionally, the covering is comprised of a hybrid polymer mixture, an example of which includes, but is not limited to, polyurethane and cellulose ester mixed to homogeneity. Preferably, the covering is applied by dipping the substrate in a solution containing a polyurethane polymer in dimethylacetamide. Preferably, the concentration of the polyurethane polymer is from about 10% to about 30% w/w. The covering preferably is oven cured such as at about 85°C for from about 30 minutes to about 60 minutes. Optionally several coats of the covering can be applied sequentially.

Optionally a bonding layer can be applied to the substrate as a precoat before the coating is applied. A preferred layer that can be used comprises a composition comprising from about 65% to about 75 % w/w tetrahydrofuran, from about 15% to about 20% w/w cyclohexanone, from about 3% to about 4% w/w polyurethane resin, from about 2.5 % to about 3.5% w/w acrylic resin, from about 1% to about 2% w/w aliphatic polyisocyanate and from about 05% to about 1.5% w/w trichloracetic acid.

The coating layer of the present invention is preferably a hydrogel. The compositions used to form the hydrogel preferably comprise a mixture of at least one and more preferably at least two, components selected from the group consisting of ethanol, polyvinylpyrrolidone,

benzyl alcohol, cyclohexanone, tetrahydrofuran, xylene, epoxy resin, acrylic resin or polymer, and n-butyl acetate. A preferred hydrogel composition comprises from about 10% to about 20% w/w ethanol, from about 2% to about 6% w/w polyvinylpyrrolidone, from about 20% to about 30% w/w benzyl alcohol, from about 45% to about 55% w/w cyclohexanone, from about 1% to about 2% w/w tetrahydrofuran, from about 2% to about 3% w/w xylene, from about 0.5% to about 1.5% w/w epoxy resin and from about 1% to about 2% w/w acrylic resin. Another preferred composition comprises from about 10% to about 20% w/w ethanol, from about 2% to about 6% w/w polyvinylpyrrolidone, from about 20% to about 30% w/w benzyl alcohol, from about 45% to about 55% w/w cyclohexanone, from about 1% to about 2% w/w tetrahydroafuran, from about 2% to about 3% w/w xylene, from about 0.5% to about 1.5% w/w epoxy resin and from about 1% to about 2% w/w acrylic polymer. A third preferred hydrogel composition comprises from about 35% to about 45% w/w ethanol, from about 20% to about 30% w/w tetrahydrofuran, from about 12% to about 20% w/w cyclohexanone, from about 10% to about 16% w/w benzyl alcohol, from about 2% to about 4% w/w acrylic resin, from about 1% to about 2.1% w/w polyvinylpyrrolidone, from about1% to about 2% w/w epoxy resin, and from about 0.9% to about 1.3% w/w n-butyl acetate.

One embodiment of the present invention incorporates physiologic and/or pharmacologic agents into the coating and optionally into the covering. In one preferred embodiment, the coating comprises an outer layer comprised of a composition comprised of from about 35% to about 45% w/w ethanol, from about 20% to about 30% w/w tetrahydrofuran, from about 12% to about 20% w/w cyclohexanone, from about 10% to about 16% w/w benzyl alcohol, from about 2% to about 4% w/w acrylic resin, from about 1% to about 2.1% w/w polyvinylpyrrolidone, from about 1% to about 2% w/w epoxy resin, from

about 0.9% to about 1.3% w/w n-butyl acetate, and from about 0.5% to about 1.5 % w/w of benzalkonium heparinate.

The present invention includes a method of providing desirable surface properties to a variety of insertable medical devices by the application of selected coverings and coatings, optionally with a binding layer. The method comprises applying one or more layers of the compositions disclosed herein to the substrate surface, in order to provide the appropriate surface for the function of the medical device.

Listed below are a series of examples of the present invention. The examples contained herein are intended to illustrate the invention but are not intended to limit the scope of the invention.

Example 1

A 0.035 " stainless steel guide wire was dipped in a solution of 25% (w/w) polyurethane polymer, ChronoFlex AR (Medical grade aromatic polycarbonate polyurethane synthesized by the addition of MDI (diphenylmethane4,4-diisocyanate) to polycarbonate diol), in dimethylacetamide, and then pulled out of the polymer solution though a 0.062" aperture in a metal disk. The sample was then oven cured at 85°C for about 30 minutes. Next, the sample was dipped in the following hydrogel solution, withdrawn, and oven dried at 85°C for about 60 minutes.

Ethanol	1.9 gm
Polyvinylpyrrolidone	0.6 gm
Benzyl alcohol	3.4 gm
Cyclohexanone	6.4 gm
Tetrahydrofuran	0.2 gm
Xylene	0.3 gm
Epotuf 38-505	0.1 gm
Paraloid® AT-63	0.2 gm

Epotuf 38-505 (Reichold, Research Triangle Park, NC) is an epoxy resin.

Paraloid® AT-63 (Rohm and Haas, Co., Philadelphia, PA) is a crosslinkable acrylic polymer with hydroxyl function.

The sample was tested for adhesion under both wet and dry conditions. The sample was dipped in Gentian Violet, Huckers Gram Stain Solution

$[(CH_3)_2NC_6H_4]_2C:C_6H_4:N(CH_3)_2Cl$; VWR, West Chester, PA, Cat No. VW3567-1] for 5 - 10 seconds, and then rinsed with running cold tap water for a few moments until the unabsorbed dye stopped running off the sample. The sample was then rubbed vigorously between the thumb and forefinger with moderate pressure while still wet to determine whether the blue dye stained coating would rub off or stay on the surface. If the coating did not rub off, it was considered to have passed the test. Next, the sample was permitted to dry under ambient room conditions for about 30 minutes. Then the sample was tested for dry adhesion by firmly pressing a 2.5 cm to 7.5 cm length of adhesive tape (Scotch® Magic™ Tape No 810, 3M, St Paul, Minnesota) onto the sample and then pulling the tape off very rapidly. Any coating on the tape was easy to see visually because it was stained with the blue dye. The tape was examined by visual inspection to determine if any coating came off on the tape. The sample was considered to have passed the dry adhesion test if no coating came off the substrate onto the tape. Flexibility was tested on appropriate samples by bending the article through a small radius 180° turn and inspecting the sample under a microscope at 30X magnification to determine if there were any breaks in the coating. The coating was considered to have passed the flexibility test if no breaks were seen in the bent sample. The sample was very flexible and the coating passed the wet and dry adhesion tests. The sample was lubricious when wet.

Example 2

A sample of 0.035" stainless steel coil guide wire was coated with the polyurethane solution as in Example 1. Next, the sample was dipped in the following hydrogel solution and withdrawn.

Ethanol	1.9 gm
Polyvinylpyrrolidone	0.5 gm
Benzyl alcohol	3.4 gm
Cyclohexanone	6.4 gm
Tetrahydrofuran	0.2 gm
Xylene	0.3 gm
Epotuf 38-505	0.1 gm
Paraloid® AT-63	0.2 gm

The coated sample was oven dried at 85°C for about 60 minutes, and tested as described in Example 1. The sample was very flexible and the coating passed the wet and dry adhesion tests. The sample was lubricious when wet.

Example 3

A stainless steel mandril was dipped in a solution of 12.5% (w/w) polyurethane resin in dimethylacetamide, and then pulled out of the polymer solution at 15 mm/second. The sample was then oven cured at 65°C for about 20 minutes. A total of three polyurethane layers were applied in this manner. Next the sample was dipped in the following hydrogel solution and withdrawn at 30 mm/second.

Hydrogel Solution C

Ethanol	39.0	% (w/w)
Tetrahydrofuran	24.0	% (w/w)
Cyclohexanone	16.0	% (w/w)
Benzyl alcohol	13.0	% (w/w)
Paraloid® AT-63	3.0	% (w/w)
Polyvinylpyrrolidone	1.7	% (w/w)
Epotuf 38-505	1.5	% (w/w)
n-Butyl acetate	1.1	% (w/w)

The coated sample was oven cured for about one hour at 75°C. The sample then was tested as described n Example 1. The sample and passed the wet and dry adhesion tests.The sample was moderately lubricious when wet.

Example 4

A stainless steel mandril was dipped in the precoat solution below for 20 seconds. The coated sample was dried for about 45 minutes at 75°C.

Precoat Solution D

Tetrahydrofuran	72.0	% (w/w)
Cyclohexanone	19.0	% (w/w)
Ethylene-acrylic acid copolymer	3.6	%(w/w)
Paraloid® AT-746	2.9	% (w/w)
Aliphatic polyisocyanate	1.2	%(w/w)
Trichloracetic acid	1.0	%(w/w)

Paraloid® AT-746 (Rohm and Haas, Co., Philadelphia, PA) is a crosslinkable acrylic polymer with hydroxyl function.

Next, three layers of the 12.5% polyurethane solution in Example 3 were applied sequentially as described in Example 3. Thereafter, a hydrogel solution as described in Example 3 was coated over the polyurethane layers as described in Example 1. The sample was tested as described in Example 1, and exhibited good flexibility and good wet and dry adhesion, and showed moderate wet lubricity.

Example 5

A stainless steel mandril was coated three times with a 12.5% polyurethane solution as described in Example 3. The sample was cured at 65°C for 20 minutes after each coating layer was applied. Next, the sample was dipped in the following hydrogel solution using the method of Example 1:

Hydrogel Solution E

Ethanol	38.6	% (w/w)
Tetrahydrofuran	24.5	% (w/w)
Cyclohexanone	15.8	% (w/w)
Benzyl alcohol	12.9	% (w/w)
Paraloid® AT-63	3.0	% (w/w)
Polyvinylpyrrolidone	1.7	% (w/w)
Epotuf 38-505	1.5	% (w/w)
n-Butyl acetate	1.0	% (w/w)
Paclitaxel	1.0	%(w/w)

The sample was oven dried for one hour at 75°C, and tested as described in Example 1 for adhesion. The sample passed the wet and dry adhesion tests. The sample was moderately lubricious when wet.

Example 6

A sample of stainless steel mandril was coated three times with a 12.5% polyurethane solution as in Example 4. It was dried for 20 minutes at 65°C after each coating application. Next, the sample was dipped in the following hydrogel solution:

Hydrogel Solution F

Ethanol	38.6	% (w/w)
Tetrahydrofuran	24.5	% (w/w)
Cyclohexanone	15.8	% (w/w)
Benzyl alcohol	12.9	% (w/w)
Paraloid® AT-63	3.0	% (w/w)
Polyvinylpyrrolidone	1.7	% (w/w)
Epotuf 38-505	1.5	% (w/w)
n-Butyl acetate	1.0	% (w/w)
Benzalkonium heparinate (HBAC)	1.0	%(w/w)

The sample was oven dried for one hour at 75°C. The sample passed the wet and dry adhesion tests described in Example 1. The sample was moderately lubricious when wet.

Example 7

A stainless steel mandril was coated three times with a 12.5% polyurethane solution as in Example 4. The sample was oven dried for 20 minutes at 60°C after each coating application. Next, the sample was dipped in the following hydrogel solution and withdrawn:

Hydrogel Solution G

Ethanol	38.6	% (w/w)
Tetrahydrofuran	24.5	% (w/w)
Cyclohexanone	15.8	% (w/w)
Benzyl alcohol	12.9	% (w/w)
Paraloid® AT-63	3.0	% (w/w)
Polyvinylpyrrolidone	1.7	% (w/w)
Epotuf 38-805	1.5	% (w/w)
n-Butyl acetate	1.0	% (w/w)
Paclitaxel	0.5	%(w/w)
HBAC	0.5	%(w/w)

The sample was oven dried for one hour at 75°C. The sample was tested for adhesion as described in Example 1 and passed the wet and dry adhesion tests. The sample was moderately lubricious when wet.

Example 8

A stainless steel madril was dipped in a Precoat having the following composition for 20 seconds and then withdrawn at 30 mm/second.

Precoat Solution H

Tetrahydrofuran	72.0	% (w/w)
Cyclohexanone	19.3	% (w/w)
Ethylene-acrylic acid copolymer	3.6	% (w/w)
Paraloid® AT-746	2.9	% (w/w)
Aliphatic polyisocyanate	1.2	% (w/w)
Trichloracetic acid	1.0	% (w/w)

The sample was dried for 30 minutes at 85°C. Next, three layers of the 12.5% polyurethane solution of Example 3 were applied as in Example 3. Thereafter, the hydrogel solution of Example 6 was coated over the polyurethane layers as described in Example 6. The sample was tested as described in Example 1 and was flexible and had good wet and dry adhesion. The sample was moderately lubricious when wet.

What is claimed is:

1. A medical device comprising:

an insertable substrate;

an elastic polymeric covering adherent to a surface of the substrate; and,

an elastic polymeric coating adherent to said covering;

wherein said coating has properties selected from the group of lubriciousness, non-lubriciousness, flexible, and expansile.

2. The device of claim 1, wherein said device is selected from the group comprising, guide wires, forceps, trochars, stents and catheters.

3. The device of claim 1 wherein said device is a stent;

the substrate of the stent comprises a framework;

said covering and said coating is attached permanently to, and extends between the elements of said framework; and,

said covering and coating remain attached to, and are stretched between, said framework when said stent is expanded.

4. The device of claim 3 wherein said framework is metal.

5. The device of claim 3 wherein said coating comprises a compound selected from the group comprising physiologic agents and pharmacologic agents.

6. The device of claim 5 wherein said agent is selected from the group comprising antiangiogenic compounds, angiogenic compounds, antineoplastic compounds, antithrombogenic compounds, thrombogenic compounds, growth factors, and anti-infective compounds.

7. The device of claim 1, wherein said substrate is selected from the group of metals, shape memory materials, non-biodegradable polymeric materials, and biodegradable polymeric materials.

8. The device of claim 1, wherein said substrate is selected from the group of stainless steel, titanium, silver, gold, platinum, aluminum, chromium, tantalum, nickel/titanium alloy, copper/zinc alloy, nickel/aluminum alloy, poly(L-lactic acid), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L,-lactic acid), poly(glycolicacid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, amino acid), cyanoacrylates, polyalkylene oxalate, polyphosphazenes, fibrin, fibrinogen, cellulose, starch collagen, hyaluronic acid, polyurethane, silicone, polyamide, polyimide, polyvinylacetal, polyethylene, polypropylene, polyvinylchloride, polyvinylacetate, polyester.

9. The device of Claim 1, wherein said covering is comprised of polyurethane.

10. The device of claim 9 wherein said covering is comprised of a hybrid polymer mixture.

11. The device of claim 10 wherein said hybrid polymer mixture comprises polyurethane and cellulose ester.

12. The device of Claim 1, wherein said coating comprises a hydrogel.

13. The device of Claim 8, wherein said hydrogel comprises compounds selected from the group consisting of polyvinylpyrrolidone, epoxy resin, acrylic polymer, acrylic resin, and polyisocyanate.

14. The device of Claim 1, wherein said coating comprises a compound with physiologic or pharmacologic activity.

15. The device of Claim 12, wherein said compound is selected from the group of compounds comprising anticoagulants, anti-platelet agents, antineoplastic agents, antimicrobial agents, anti-angiogenic agents and angiogenic agents.

16. The device of Claim 8, wherein said coating comprises a composition consisting of ethanol, polyvinylpyrrolidone, benzyl alcohol, cyclohexanone, tetrahydrafuran, xylene, epoxy resin and acrylic resin.

17. The device of Claim 16, wherein said coating comprises a composition consisting of from about 10% to about 20% w/w ethanol, from about 2% to about 6% w/w polyvinylpyrrolidone, from about 20% to about 30% w/w benzyl alcohol, from about 45% to about 55% w/w cyclohexanone, from about 1% to about 2% w/w tetrahydrafuran, from about 2% to about 3% w/w xylene, from about 0.5% to about 1.5% w/w epoxy resin and from about 1% to about 2% w/w acrylic resin.

18. The device of Claim 8, wherein said coating comprises a composition consisting of ethanol, polyvinylpyrrolidone, benzyl alcohol, cyclohexanone, tetrahydrafuran, xylene, epoxy resin and acrylic polymer.

19. The device of Claim 18, wherein said coating comprises a composition consisting of from about 10% to about 20% w/w ethanol, from about 2% to about 6% w/w polyvinylpyrrolidone, from about 20% to about 30% w/w benzyl alcohol, from about 45% to about 55% w/w cyclohexanone, from about 1% to about 2% w/w tetrahydrafuran, from about 2% to about 3% w/w xylene, from about 0.5% to about 1.5% w/w epoxy resin and from about 1% to about 2% w/w acrylic polymer.

20. The device of Claim 8, wherein said coating comprises a composition consisting of ethanol, tetrahydrafuran, cyclohexanone, benzyl alcohol, acrylic resin, polyvinylpyrrolidone, epoxy resin, and n-butyl acetate.

21. The device of Claim 20, wherein said coating comprises a composition consisting of from about 35% to about 45% w/w ethanol, from about 20% to about 30% w/w tetrahydrafuran, from about 12% to about 20% w/w cyclohexanone, from about 10% to about 16% w/w benzyl alcohol, from about 2% to about 4% w/w acrylic resin, from about 1% to about 2.1% w/w polyvinylpyrrolidone, from about1% to about 2% w/w epoxy resin, and from about 0.9% to about 1.3% w/w n-butyl acetate.

22. The device of Claim 1, wherein said covering comprises a composition consisting of from about 65% to about 75 % w/w tetrahydrofuran, from about 15% to about 20% w/w cyclohexanone, from about 3% to about 4% w/w polyurethane resin, from about 2.5 % to about 3.5% w/w acrylic resin, from about 1% to about 2% w/w aliphatic polyisocyanate and from about 05% to about 1.5% w/w trichloracetic acid.

23. The device of Claim 22 wherein said coating comprises at least one layer comprised of polyurethane.

24. The device of claim 23 wherein said coating contains at least one compound selected from the group comprising paclitaxel and benzalkonium heparinate.

25. The device of Claim 24 wherein the concentration of said compound in said coating is from about 0.3 % to about 1.2% w/w.

26. The device of Claim 25 wherein said coating comprises an outer layer comprised of a composition comprised of from about 35% to about 45% w/w ethanol, from about 20% to about 30% w/w tetrahydrofuran, from about 12% to about 20% w/w cyclohexanone, from about 10% to about 16% w/w benzyl alcohol, from about 2% to about 4% w/w acrylic resin, from about 1% to about 2.1% w/w polyvinylpyrrolidone, from about1% to about 2% w/w epoxy resin, from about 0.9% to about 1.3% w/w n-butyl acetate, and from about 0.5% to about 1.5 % w/w of benzalkonium heparinate.

27. A method of modifying the surface properties of an insertable medical device comprising:
providing the substrate of said medical device with an elastic polymeric covering; and coating said covering with a polymeric coating with properties selected from the group of lubricious, non-lubricious, flexible, elastic and expansile.

28. The method of Claim 27 wherein said covering comprises a composition consisting of from about 65% to about 75 % w/w tetrahydrofuran, from about 15% to about 20% w/w cyclohexanone, from about 3% to about 4% w/w polyurethane resin, from about 2.5 % to about 3.5% w/w acrylic resin, from about 1% to about 2% w/w aliphatic polyisocyanate and from about 05% to about 1.5% w/w trichloracetic acid.

29. The method of Claim 28 wherein said coating comprises at least one layer of a polyurethane compound and an outer layer of a compound comprising from about 35% to about 45% w/w ethanol, from about 20% to about 30% w/w tetrahydrafuran, from about 12% to about 20% w/w cyclohexanone, from about 10% to about 16% w/w benzyl alcohol, from about 2% to about 4% w/w acrylic resin, from about 1% to about 2.1% w/w polyvinylpyrrolidone, from about1% to about 2% w/w epoxy resin, from about 0.9% to about 1.3% w/w n-butyl acetate, and from about 0.5% to about 1.5 % w/w of benzalkonium heparinate.